114

(3)

No. 08-624

Supreme Court, U.S.
FILED
DEC 10 2003
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

FOREST LABORATORIES, INC.,
FOREST LABORATORIES HOLDINGS, LTD.,
and H. LUNDBECK A/S,

Petitioners,

v.

CARACO PHARMACEUTICAL LABORATORIES, LTD.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF OF AMICUS CURIAE PFIZER INC. IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI

DIMITRIOS T. DRIVAS
Counsel of Record
JEFFREY J. OELKE
ADAM GAITAN
BRENDAN G. WOODARD
WHITE & CASE LLP
Attorneys for Amicus Curiae Pfizer Inc.
1155 Avenue of the Americas
New York, NY 10036
(212) 819-8200

TABLE OF CONTENTS

Page

TABLE OF CITED AUTHORITIES iii

INTEREST OF *AMICUS CURIAE* 1

SUMMARY OF ARGUMENT 3

ARGUMENT 5

I. The Federal Circuit's Attempt To Create Jurisdiction For ANDA Filers Contravenes Express Congressional Intent 5

A. Congress Did Not Create a New Cause of Action for ANDA Filers ... 5

B. Congress Has Expressly Rejected Automatic Jurisdiction 8

C. The Federal Circuit Failed to Consider the Relevant Legislative History in Proper Context 10

II. Exercise of Jurisdiction in This Case Would Undermine Article III of the Constitution and Yield an Unconstitutional Advisory Opinion 11

Contents

Page

III. The Opinion Conflicts with Other Federal Circuit Decisions 14

A. Covenants Not To Sue 14

B. Tracing Injury to Compliance with a Statutory Requirement 17

IV. The Federal Circuit Cannot Substitute Its Own Policy Concerning The 180-Day Exclusivity Period For That Of Congress 19

CONCLUSION 21

TABLE OF CITED AUTHORITIES

Page

Cases

Aetna Life Ins. Co. v. *Haworth*,
300 U.S. 227 (1937) 9

Alabama State Fed'n of Labor v. *McAdory*,
325 U.S. 450 (1945) 13

Apotex Inc. v. *Pfizer Inc.*,
No. 04-1463, 125 Fed. Appx. 987,
2005 WL 821393 (Fed. Cir. April 11, 2005) ... 2

Aschcroft v. *Mattis*,
431 U.S. 171 (1977) 12, 13

Benitec Australia, Ltd. v. *Nucleonics, Inc.*,
495 F.3d 1340 (Fed. Cir. 2007) 14

Cardinal Chem. Co. v. *Morton Int'l, Inc.*,
508 U.S. 83 (1993) 14

Consumer Prod. Safety Comm'n
v. *GTE Sylvania, Inc.*,
447 U.S. 102 (1980) 5

Demby v. *Schweiker*,
671 F.2d 507 (D.C. Cir. 1981) 10

Dickinson v. *Petroleum Conversion Corp.*,
338 U.S. 507 (1950) 14

Cited Authorities

Page

Fina Oil and Chem. Co. v. *Ewen*,
123 F.3d 1466 (Fed. Cir. 1997) 10

Griffith v. *Oceanic Contractors, Inc.*,
458 U.S. 564 (1982) 5

Hewitt v. *Helms*,
482 U.S. 755 (1987) 13

Janssen Pharmaceutica, N.V. v.*Apotex, Inc.*,
540 F.3d 1353 (Fed. Cir. 2008) 15, 16

John Hancock Mutual Life Ins. Co. v. *Bartels*,
308 U.S. 180 (1939) 14

Lawyer v. *Dep't of Justice*,
521 U.S. 567 (1997) 13

Maggio v. *Zeitz*,
333 U.S. 56 (1948) 14

Merck & Co., Inc. v. *Hi-Tech Pharmacal Co., Inc.*,
482 F.3d 1317 (Fed. Cir. 2007) 18

Neonatology Assocs., P.A. v. *Comm'r*,
293 F.3d 128 (3rd. Cir. 2002) 2

Nippon Steel Corp. v. *U.S.*,
458 F.3d 1345 (Fed. Cir. 2006) 15

Cited Authorities

Page

North Carolina v. *Rice*,
404 U.S. 244 (1971) 13

Prasco, LLC v. *Medicis Pharm. Corp.*,
537 F.3d 1329 (Fed. Cir. 2008) 17, 18

Preiser v. *Newkirk*,
422 U.S. 395 (1975) 12, 13

Princeton Univ. v. *Schmid*,
455 U.S. 100 (1982) 12, 13

Raines v. *Byrd*,
521 U.S. 811 (1997) 9

Ranbaxy Labs. Ltd. v. *Leavitt*,
469 F.3d 120 (D.C. Cir. 2006) 20

State Contracting & Eng'g Corp.
v. *Condotte Am., Inc.*,
346 F.3d 1057 (Fed. Cir. 2003) 18

Teva Pharms. USA, Inc. v. *Pfizer Inc.*,
395 F.3d 1324 (Fed. Cir. 2005) 2, 20

United Pub. Workers v. *Mitchell*,
330 U.S. 75 (1947) 12

Cited Authorities

Page

Valley Forge Christian Coll.
v. *Ams. United for Separation of Church & State, Inc.*,
454 U.S. 464 (1982) 9

Warner-Jenkinson Co.
v. *Hilton Davis Chem. Co.*,
520 U.S. 17 (1997) 14

Constitutional Provision

U.S. CONST. art. III, § 2, cl. 1 ..... 9, 12

Statutes

21 U.S.C. § 355(b)(1) 3, 17

21 U.S.C. § 355(j)(5)(B)(iii) 6

21 U.S.C. § 355(j)(5)(B)(iv) 19, 20

21 U.S.C. § 355(j)(5)(C) 4, 5, 6, 7, 8

21 U.S.C. § 355(j)(5)(C)(i)(I)(bb) 6

21 U.S.C. § 355(j)(5)(C)(i)(I)(cc) 6

21 U.S.C. § 355(j)(5)(C)(i)(III) 6

28 U.S.C. § 2201 ..... 3, 4, 5, 6, 7

Cited Authorities

Page

28 U.S.C. § 2201(b) 7, 8

28 U.S.C. § 2202 5

35 U.S.C. § 271(e)(5) 6, 7, 10

35 U.S.C. § 287 17

35 U.S.C. § 287(a) 18

Rules

SUP. CT. R. 37 2

Session Laws

Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) 1

Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) 4, 19

Conference Report

H.R. REP. No. 108-391 (2003) (Conf. Rep.) 10, 11

Cited Authorities

Page

Bill

Prescription Drug and Medicare Improvement Act of 2003, S. 1, 108th Cong. (2003) 9

Congressional Record

149 CONG. REC. S8691 (daily ed. June 26, 2003) 9, 20

149 CONG. REC. S15,567 (daily ed. Nov. 22, 2003) ... 7, 10

149 CONG. REC. S15,885 (daily ed. Nov. 25, 2003) ... 11

149 CONG. REC. S15,915 (daily ed. Nov. 25, 2003) ... 10

149 CONG. REC. S16,104 (daily ed. Dec. 9, 2003) 10

INTEREST OF *AMICUS CURIAE*[1]

Pfizer Inc. ("Pfizer") is one of the world's largest innovator pharmaceutical companies, dedicated to developing and commercializing safe, effective, and affordable medicines. Pfizer invests heavily in research and product development to bring to market new products that address major unmet health care needs. Due to the significance of the Federal Circuit Court of Appeals' decision to innovator companies such as Pfizer and Forest, and to the pharmaceutical industry as a whole, Pfizer submits its *amicus curiae* brief in support of Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., and H. Lundbeck A/S's (collectively, "Forest") Petition for a Writ of Certiorari (the "Petition").

Acquiring and enforcing patents is critical to the mission of innovator pharmaceutical companies like Pfizer. Pfizer frequently participates in patent litigation against generic pharmaceutical manufacturers pursuant to the legal framework established by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (the "Hatch-Waxman Act"). Indeed, Pfizer has been a party in cases in which the Court of Appeals for the Federal Circuit addressed the issue before the Court: declaratory judgment jurisdiction in the Hatch-

---

[1] No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae*, or their counsel, made a monetary contribution to its preparation or submission. The parties have consented to the filing of this brief. The parties have been given at least 10 days notice of the intention to file this *amicus* brief.

Waxman context. See, e.g., Teva Pharms. USA, Inc. v. Pfizer Inc., 395 F.3d 1324 (Fed. Cir. 2005); Apotex Inc. v. Pfizer Inc., No. 04-1463, 125 Fed. Appx. 987, 2005 WL 821393 (Fed. Cir. April 11, 2005). Pfizer has a continued interest in ensuring that the Federal Circuit correctly and consistently applies the test for declaratory judgment jurisdiction in the Hatch-Waxman context. In particular, Pfizer has an interest in ensuring that it is not required to risk its patents in litigation every time a generic drug manufacturer files an Abbreviated New Drug Application ("ANDA"). In the absence of an actual controversy with the generic company, and where Pfizer has no business reason for filing suit for infringement, it should not have to engage in litigation.

Pfizer submits its *amicus* brief based on its experience with the relevant laws. Pursuant to this Court's Rules, *amicus* briefs are appropriate when the party submitting the brief "brings to the attention of the Court relevant matter not already brought to its attention by the parties." SUP. CT. R. 37; see also Neonatology Assocs., P.A. v. Comm'r, 293 F.3d 128, 130-31 (3rd. Cir. 2002) (Alito, J.). Pfizer's brief provides, inter alia, relevant statutory background and legislative history that gives meaningful context to the Hatch-Waxman Act amendments addressed in the Federal Circuit's majority opinion and will aid in the Court's consideration of Forest's Petition.

SUMMARY OF ARGUMENT

The Court should review and reverse the Federal Circuit's ruling that Forest's covenant not to sue Caraco Pharmaceutical Laboratories, Ltd. ("Caraco"), a generic drug manufacturer, for patent infringement did not eliminate the patent controversy between the parties (the "Opinion"). The Opinion raises important constitutional and jurisdictional concerns regarding declaratory patent actions brought under 28 U.S.C. § 2201, and conflicts with longstanding and recent Federal Circuit precedent. It also contravenes the statutory language and legislative history of the Hatch-Waxman laws by creating a new cause of action for generic manufacturers, and undermines Congress's express incentive to ANDA filers that are the first to challenge patents covering an innovator drug product. Further, the Opinion undermines the Article III "case or controversy" requirement and obligates Forest to litigate, and the trial court to resolve, a hypothetical patent conflict that will result in the improper issuance of an advisory opinion that could have no effect on Forest's rights and duties. The Federal Circuit has, in effect, rewritten the Hatch-Waxman Act in a manner exceeding its judicial authority.

Courts have long held that a covenant not to sue for infringement eliminates any controversy between a patentee and a potential infringer. The Federal Circuit's decision departs from this precedent and predicates declaratory judgment jurisdiction upon non-party IVAX Pharmaceuticals, Inc.'s ("IVAX") eligibility for generic exclusivity under the Hatch-Waxman Act. The Federal Circuit determined that first-ANDA-filer IVAX's exclusivity period was an "injury" to declaratory plaintiff and later-ANDA-filer Caraco. The Federal Circuit then "traced" that injury to Forest's listing of the patent-in-suit in the publication *Approved Drug Products With Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book," notwithstanding that Forest was required to list its patent under 21 U.S.C. § 355(b)(1).

In finding jurisdiction for Caraco's declaratory judgment action, the Federal Circuit primarily relied on the "Civil Action to Obtain Patent Certainty," codified at 21 U.S.C. § 355(j)(5)(C). Congress enacted the Civil Action to Obtain Patent Certainty, among other amendments to the Hatch-Waxman laws, as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (the "Medicare Amendments"). The Federal Circuit failed to consider the relevant legislative history of the Medicare Amendments, addressing in isolation only the comments of Senator Kennedy concerning the Civil Action to Obtain Patent Certainty. Senator Kennedy did not sponsor the Medicare Amendments, and in fact voted against them. As outlined in Pfizer's *amicus* brief, those comments, considered in context, and the balance of the relevant legislative history, mandate the dismissal of Caraco's declaratory judgment action.

In enacting the Medicare Amendments, Congress actually considered, but rejected, the creation of automatic declaratory jurisdiction for generic drug manufacturers. Congress instead indicated that courts should apply the same standard for subject matter jurisdiction under the Declaratory Judgment Act, 28 U.S.C. § 2201, in the Hatch-Waxman context as in any other patent case. The Opinion is therefore at odds with the legislative history of the relevant statute which, unlike Senator Kennedy's comments about the Civil Action to Obtain Patent Certainty, is germane to the jurisdictional question in this case. The Opinion also conflicts with recent Federal Circuit precedent holding that a covenant not to sue did moot the controversy between the patentee and the potential generic infringer, and that a patentee's compliance with a statutory requirement, like listing patents in the Orange Book, could not create declaratory judgment jurisdiction.

Given the substantial jurisdictional and constitutional concerns raised by the Opinion, and because the Federal

Circuit failed to apply the same jurisdictional test as it would in any other patent case, the Court should, in consideration of the relevant legislative history and case law outlined in Pfizer's brief, grant Forest's Petition.

ARGUMENT

I. THE FEDERAL CIRCUIT'S ATTEMPT TO CREATE JURISDICTION FOR ANDA FILERS CONTRAVENES EXPRESS CONGRESSIONAL INTENT

The Court of Appeals for the Federal Circuit must apply the law as enacted and according to Congressional intent. Griffith v. Oceanic Contractors, Inc., 458 U.S. 564, 576 (1982); Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc., 447 U.S. 102, 123-24 (1980). The Federal Circuit disregarded that obligation and overstepped its judicial authority in this case. As both the statutory text and legislative history of the relevant Hatch-Waxman provisions make clear, Congress did not create a unique cause of action for ANDA filers. Moreover, Congress expressly rejected automatic jurisdiction for ANDA filers and stated its expectation that courts would apply the established jurisdictional test for patent declaratory actions. Because the Federal Circuit failed to apply the Hatch-Waxman law according to clear Congressional intent, review and reversal is appropriate.

A. Congress Did Not Create a New Cause of Action for ANDA Filers

Caraco brought its action under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the provision of the Medicare Amendments establishing the Civil Action to Obtain Patent Certainty, 21 U.S.C. § 355(j)(5)(C). The Federal Circuit primarily relied on the latter provision in finding jurisdiction for Caraco's declaratory judgment action. The statutory language and legislative history of the Civil Action to Obtain Patent Certainty make clear, however, that ANDA filers like Caraco must satisfy the same

jurisdictional requirements under 28 U.S.C. § 2201 as any other patent challenger.

Congress enacted the Civil Action to Obtain Patent Certainty, among other changes to the Hatch-Waxman laws, as part of the Medicare Amendments. Long before the Medicare Amendments, the Hatch-Waxman Act itself allowed an ANDA filer to bring an action under 28 U.S.C. § 2201 with respect to an Orange Book-listed patent, under certain conditions and provided that the standards for declaratory judgment jurisdiction were met. See 21 U.S.C. § 355(j)(5)(B)(iii) (1984). With the Medicare Amendments, Congress imposed additional conditions on an ANDA filer's ability to bring a declaratory action under 28 U.S.C. § 2201.[2] See 21 U.S.C. § 355(j)(5)(C) (2003). Both the pre- and post-Medicare Amendments Hatch-Waxman provisions make clear that, even if the ANDA filer meets the Act's requirements, any declaratory judgment action it might file must be brought under 28 U.S.C. § 2201.

The Medicare Amendments also amended the patent laws, creating subsection (e)(5) of 35 U.S.C. § 271, entitled "Infringement of patent." The Federal Circuit relied on this new subsection for "extended jurisdiction over Civil Actions to Obtain Patent Certainty." The subsection makes no

---

[2] These additional conditions include that an ANDA filer that alleges non-infringement of the listed patent must now provide an "offer of confidential access" to its ANDA. 21 USC §§ 355(j)(5)(C)(i)(I)(cc), (III). Congress also clarified that an ANDA filer could not bring a declaratory judgment action if it had been sued by the patentee or NDA-holder within the 45-day period. 21 USC § 355(j)(5)(C)(i)(I)(bb). The original Hatch-Waxman Act stated only that a declaratory judgment action could not be brought within the 45-day period. See 21 U.S.C. § 355(j)(5)(B)(iii) (1984).

reference to "Civil Actions to Obtain Patent Certainty," however, as a basis for declaratory jurisdiction or otherwise. See 35 U.S.C. § 271(e)(5). In fact, it states that ANDA filers are required to bring and maintain their declaratory judgment actions under 28 U.S.C. § 2201: courts in ANDA cases "shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed." 35 U.S.C. § 271(e)(5) (emphasis added).

The legislative history of the Medicare Amendments also expressly states that Congress did not intend to create a new cause of action or to expand the existing authority for ANDA filers under 28 U.S.C. § 2201. Senator Hatch, co-sponsor of the original Hatch-Waxman Act, stated with respect to the Medicare Amendments:

> I also want to make explicit, the implicit – that nothing in this new language pertaining to pharmaceutical patent-related declaratory judgments creates a new cause of action separate from the existing authority under title 28.

149 CONG. REC. S15,567 (daily ed. Nov. 22, 2003). Declaratory judgment actions under section 2201 maintain the jurisdictional requirement of an underlying patent dispute between the patentee and the patent challenger.

As is clear from the statutory text and legislative history, section 2201 of title 28 is the sole jurisdictional basis for a declaratory judgment action by an ANDA filer. Section 2201 itself provides no support for expanded jurisdiction in ANDA cases, but actually emphasizes that declaratory judgment jurisdiction in such cases is subject to specific limitations, including the restrictions discussed above and set forth in the new Civil Action to Obtain Patent Certainty provision, 21 U.S.C. § 355(j)(5)(C). Section 2201(b) reads as follows:

> (b) For limitations on actions brought with respect to drug patents see section 505 or 512 of the Federal Food, Drug, and Cosmetic Act.

28 U.S.C. § 2201(b) (emphasis added).[3] Contrary to the Federal Circuit's finding, therefore, there is simply no statutory basis for finding declaratory judgment jurisdiction in the Hatch-Waxman context when none would exist outside of it.

B. Congress Has Expressly Rejected Automatic Jurisdiction

By endorsing this basis of jurisdiction, the Opinion essentially creates automatic jurisdiction for all generic patent challengers. If an innovator company's irrevocable covenant not to sue does not eliminate a patent controversy, a later-filing generic manufacturer could bring a declaratory action solely to obtain a judgment enabling it under the Hatch-Waxman scheme to attack the 180-day exclusivity of a first-filer, a non-party to the suit. In effect, the innovator could be forced to risk its patents in litigation solely to further the declaratory plaintiff's competition with its generic-manufacturer rivals, not to resolve an actual controversy involving the innovator. In enacting the Medicare Amendments, however, Congress contemplated the jurisdictional test that should be applied in ANDA cases. Congress considered but rejected "automatic" declaratory judgment jurisdiction, instead providing that courts should apply the same test as in any declaratory patent action, finding jurisdiction where appropriate.

---

[3] The new Civil Action to Obtain Patent Certainty provision with respect to ANDAs is set forth in subsection 505(j)(5)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(5)(C)).

The Senate proposed creating automatic jurisdiction in Hatch-Waxman cases. Prescription Drug and Medicare Improvement Act of 2003, S. 1, 108th Cong. § 702(c) (2003). The Senate's proposal failed to become law, however, because of concerns about the constitutionality of legislating the existence of subject matter jurisdiction. Article III of the Constitution limits the judicial power of the United States to the resolution of "cases" and "controversies." U.S. CONST. art. III, § 2, cl. 1; Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc., 454 U.S. 464, 471 (1982). "No principle is more fundamental to the judiciary's proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases and controversies." Raines v. Byrd, 521 U.S. 811, 818 (1997) (citation omitted). Declaratory actions are appropriate only when there is an actual controversy. See, e.g., Aetna Life Ins. Co. v. Haworth, 300 U.S. 227, 239-241 (1937).

The Senate recognized that creating automatic declaratory judgment jurisdiction by statute could contravene Article III of the Constitution:

> At our June 17th hearing, DOJ did not present the Judiciary Committee with its final opinion on the matter but Mr. Sheldon Bradshaw, Deputy Assistant Attorney General, Office of Legal Counsel, noted, "that the actual case of [sic] controversy requirement is constitutionally compelled rather than statutorily required. And as a result, Congress can't simply create a case or controversy by statute but the plaintiffs must establish the constitutional requirement for bringing the case."... I have requested the Department of Justice for its formal views on this language.

149 CONG. REC. S8691 (daily ed. June 26, 2003) (statement of Sen. Hatch) (emphasis added). After the Department of

Justice determined that the Senate declaratory judgment provision was unconstitutional, 149 CONG. REC. S15,567 (daily ed. Nov. 22, 2003) (statement of Sen. Hatch), Congress "correct[ed] the constitutional flaw in the Senate-passed bill." 149 CONG. REC. S16,104 (daily ed. Dec. 9, 2003) (statement of Sen. Hatch). Consequently, the bill that became new 35 U.S.C. § 271(e)(5) did not contain the automatic jurisdiction language of the earlier bill.

Instead, in the Conference Report, and elsewhere in the legislative record, Congress indicated that it expected courts to apply the same jurisdictional test in the Hatch-Waxman context as in any other patent case. H.R. REP. NO. 108-391, at 836 (2003) (Conf. Rep.) (stating that the conferees did not intend for courts to modify their application of the jurisdictional requirements under Article III, and citing to a non-Hatch Waxman case, Fina Oil & Chem. Co. v. Ewen, 123 F.3d 1466 (Fed. Cir. 1997)). A conference report is the primary authority for interpreting statutes based on legislative history. Demby v. Schweiker, 671 F.2d 507, 510 (D.C. Cir. 1981) (MacKinnon, Circuit Judge).

C. The Federal Circuit Failed to Consider the Relevant Legislative History in Proper Context

The Federal Circuit considered only certain remarks of Senator Kennedy in concluding that "delay" caused by a generic competitor's 180-day exclusivity period was the type of injury that the Civil Action to Obtain Patent Certainty was meant to redress. Senator Kennedy did not sponsor the Medicare Amendments, and in fact voted against the Amendments. See 149 CONG. REC. S15,915 (daily ed. Nov. 25, 2003), so his comments are of little use in determining Congress's intent. Moreover, Senator Kennedy's comments, considered in the context of the Conference Report, indicate that the 180-day exclusivity period did not create the type of "delay" in FDA approval of ANDAs that concerned Congress.

As stated in the Conference Report:

> The conferees expect courts to find jurisdiction, where appropriate, to prevent an improper effort to delay infringement litigation between generic drug manufacturers and pioneer drug companies.

H.R. REP. NO. 108-391, at 836 (2003) (Conf. Rep.). This statement provides context for the remarks of Senator Kennedy which directly addressed the significance of covenants not to sue (and which the Federal Circuit wrongly dismissed in a footnote):

> We believe that the only circumstance in which a case or controversy might not exist would arise in the rare circumstance in which the patent owner and brand drug company have given the generic applicant a covenant not to sue, or otherwise formally acknowledge that the generic applicant's drug does not infringe.

149 CONG. REC. S15,885 (daily ed. Nov. 25, 2003). The Federal Circuit discounted these comments of Senator Kennedy because they were made at a time when the Federal Circuit applied solely the "reasonable-apprehension" test for determining whether a declaratory judgment action satisfied Article III. However, Senator Kennedy's remarks refer to "case or controversy," not a "reasonable apprehension of suit." As the Conference Report makes clear, in enacting the Civil Action to Obtain Patent Certainty provision, Congress was principally concerned with <u>delayed</u> litigation between the innovator company and the ANDA filer. A covenant not to sue eliminates that concern.

II. EXERCISE OF JURISDICTION IN THIS CASE WOULD UNDERMINE ARTICLE III OF THE CONSTITUTION AND YIELD AN UNCONSTITUTIONAL ADVISORY OPINION

The Opinion disregards constitutional limitations on the judiciary. Article III courts are prohibited from issuing

advisory opinions absent a constitutionally-required "case or controversy." See U.S. CONST. art. III, § 2, cl. 1; Preiser v. Newkirk, 422 U.S. 395, 401-02 (1975). A declaratory judgment action must pose "a real and substantial controversy admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts" in order for jurisdiction to lie. Preiser, 422 U.S at 401. Forest's covenant not to sue eliminated any controversy between Forest and Caraco. The Opinion thus compels an impermissible advisory opinion from the trial court which would be premised on a hypothetical: that Forest could assert its patent against Caraco. The resolution of this hypothetical situation, should Forest prevail, could result in relief that would have no legal effect on Forest's rights and duties.

Article III courts "do not sit to decide hypothetical issues or to give advisory opinions about issues as to which there are not adverse parties." Princeton Univ. v. Schmid, 455 U.S. 100, 102 (1982) (per curiam). A "hypothetical threat" of adverse action is insufficient to satisfy Article III in declaratory judgment actions – a court may address a case "only when the interests of litigants require the use of . . . judicial authority for their protection against actual interference." United Public Workers v. Mitchell, 330 U.S. 75, 90 (1947); see also Preiser, 422 U.S. at 402 (requiring controversy "between parties having adverse legal interests, of sufficient immediacy and reality") (emphasis in original). Nor can a court exercise declaratory judgment jurisdiction based on what "would have been" absent intervening circumstances. Ashcroft v. Mattis, 431 U.S. 171, 172 (1977).

Caraco requires no intervention to protect against Forest's "actual interference." Indeed, Forest's covenant bars it from interfering with Caraco's attempts to market a generic product. The Opinion nonetheless relies on Forest's patent ownership, and the listing of that patent in the Orange

Book, to create a hypothetical conflict between Forest and Caraco. The Opinion requires an Article III court to assess whether Caraco would infringe Forest's patent absent Forest's covenant. Whether Caraco infringes Forest's patent while Forest cannot sue for infringement is no more justiciable, however, than assessing whether a party would have been liable absent a particular defense, or whether regulations would have been permissible had they not been amended. See Princeton, 455 U.S. at 102-03; Aschcroft, 431 U.S. at 172. Deciding such an "abstract, hypothetical, [and] contingent question[ ]" is plainly unconstitutional. Alabama State Fed'n of Labor v. McAdory, 325 U.S. 450, 461 (1945).

Moreover, federal courts may not "decide questions that cannot affect the rights of litigants in the case before them" See, e.g., Preiser, 422 U.S. at 401; North Carolina v. Rice, 404 U.S. 244, 246 (1971). Indeed, the touchstone of a "case or controversy" is "the settling of some dispute which affects the behavior of the defendant towards the plaintiff." Lawyer v. Dep't of Justice, 521 U.S. 567, 579-80 (1997) (quoting Hewitt v. Helms, 482 U.S. 755, 761 (1987)) (emphasis in original). This Court has recognized that actions taken by the parties outside of court may render the court unable to affect a party's rights and obligations with a judgment, thus rendering any subsequent judicial opinion advisory in nature. Preiser, 422 U.S. at 401-04 (dismissing because act giving rise to alleged harm had been unilaterally rectified by defendant); Princeton, 455 U.S. at 102 (dismissing because defendant amended regulations at issue in opinion below).

Because of the covenant, a favorable decision for Forest in a hypothetical patent controversy with Caraco could not impact Forest's rights as against Caraco. Even if Forest prevailed in the underlying infringement lawsuit, it could not enforce its patent rights against Caraco, a result which would have no practical effect upon Forest's rights or behavior. Such a decision is an unconstitutional advisory opinion.

III. THE OPINION CONFLICTS WITH OTHER FEDERAL CIRCUIT DECISIONS

This Court has recognized that, in light of the Federal Circuit's nationwide appellate jurisdiction in patent cases, conflicts in the rulings of the Federal Circuit may warrant granting certiorari. See, e.g., Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 21 (1997) (noting that divisions within Federal Circuit warrant Supreme Court review); Cardinal Chem. Co. v. Morton Int'l, Inc., 508 U.S. 83, 89 (1993) (noting that certiorari was warranted in Federal Circuit patent case because uniformity of patent law "is a matter of special importance to the entire Nation"); see also, e.g., Dickinson v. Petroleum Conversion Corp., 338 U.S. 507, 508 (1950) (granting certiorari "because of [an] intracircuit conflict"); Maggio v. Zeitz, 333 U.S. 56, 59 (1948) (addressing "conflicting views" within Second Circuit on subject of fraudulent bankruptcy); John Hancock Mutual Life Ins. Co. v. Bartels, 308 U.S. 180, 181 (1939) (granting certiorari because of conflict in rulings of Fifth Circuit).

The Opinion illustrates two points of conflict within the Federal Circuit: (1) whether a covenant not to sue moots any controversy between a patentee and the potential infringer, and (2) whether a patentee's compliance with a statutory requirement can create a justiciable Article III controversy between it and an alleged infringer.

A. Covenants Not To Sue

The Federal Circuit's overwhelming precedent establishes that a covenant not to sue moots any controversy between a patentee and a potential infringer. Even following the demise of the two-part "reasonable apprehension" test as the sole basis of jurisdiction, the Federal Circuit has held that an irrevocable covenant not to sue moots any controversy between a patentee and a potential infringer. Benitec Australia, Ltd. v. Nucleonics, Inc., 495 F.3d 1340, 1347-48 (Fed. Cir. 2007).

In the Opinion, the Federal Circuit did not purport to overrule its precedent concerning covenants not to sue, nor could it, Nippon Steel Corp. v. U.S., 458 F.3d 1345, 1351 n.3 (Fed. Cir. 2006). Instead, the Federal Circuit held that "Forest's covenant not to sue did not eliminate the controversy" between the parties in the context of Hatch-Waxman because of the competitive advantage sought by Caraco concerning the 180-day exclusivity period. (Op. at 2.) Five months later, however, a different panel of the Federal Circuit reached the opposite conclusion in Janssen Pharmaceutica, N.V. v. Apotex, Inc., 540 F.3d 1353 (Fed. Cir. 2008). In Janssen, the Federal Circuit held that a covenant not to sue did moot the controversy, and did not permit the later-filing declaratory plaintiff to use a declaratory judgment action against the innovator to prematurely trigger the first-filer's exclusivity period.

In Janssen, the innovator company, Janssen, listed three patents in the Orange Book with respect to its drug Risperdal®. Id. at 1357. First-filer Teva Pharmaceuticals USA, Inc. ("Teva") challenged two of those patents, making it eligible for 180-days of generic exclusivity. Id. at 1358. Janssen declined to sue on the two challenged patents, rendering Teva's ANDA approvable upon the expiration of the third, unchallenged patent (the "'663 patent"). Id.

Apotex, the declaratory plaintiff in Janssen, filed a later ANDA for Risperdal®. Apotex stipulated to the infringement and validity of the '663 patent and sought declaratory judgments with respect to the other two patents. Id. Janssen granted Apotex a covenant not to sue on those two patents and moved to dismiss Apotex's counterclaims. Id. at 1358-59. Apotex opposed that motion, arguing that the inability to launch its product immediately after the '663 patent expired due to Teva's 180-day exclusivity period created a controversy between Janssen and Apotex. Id. at 1359.

The district court granted Janssen's motion and dismissed the case. The Federal Circuit affirmed, holding that Apotex's inability to launch its product at the same time as Teva – immediately upon expiration of the '663 patent – did not create a justiciable controversy between Janssen and Apotex. The delay of Apotex's launch, the court held instead, was "a result envisioned by the Hatch-Waxman Act." Id. at 1361. The court attempted to distinguish its earlier Opinion in this case: "[U]nlike Caraco, Apotex cannot claim that at the time of the district court's dismissal it was being excluded from selling a noninfringing product by an invalid patent – it stipulated to the validity of the '663 patent." Id.

Notwithstanding the Federal Circuit's attempt to distinguish the Opinion, the Janssen and Caraco decisions plainly conflict. In both cases, the generic manufacturer sought a declaratory judgment in order to trigger a third party's exclusivity period. Id. at 1360 ("[I]f Apotex is successful on its declaratory judgment action, Teva's exclusivity period will be triggered . . . ."), 1361 ("Caraco wanted to be able to challenge both patents and if successful, this would trigger Ivax's 180-day exclusivity period . . . ."). In both cases, the patentee granted the generic manufacturer a covenant not to sue. The Janssen court found that there was no justiciable controversy regarding the first filer's exclusivity period, while the Caraco court reached the opposite conclusion.

The Hatch-Waxman Act is complex, and Hatch-Waxman cases frequently involve multiple patents and include and affect numerous generic defendants. The tenuous factual distinction drawn by the Janssen court will undoubtedly produce conflicting decisions in the future, both within the Federal Circuit and in the district courts. While this Court has acknowledged that decisions regarding jurisdiction over declaratory judgment cases may be fact-sensitive, the complexity of Hatch-Waxman cases requires a clear delineation of the effects of covenants not to sue on Article

III jurisdiction. Without such delineation, future panels of the Federal Circuit will determine declaratory judgment jurisdiction based on the panel's view of the fairness in each case of allowing the second-filer to attempt to trigger, prematurely, the non-party first-filer's exclusivity period. As discussed below, the Federal Circuit cannot substitute its own policy concerning generic exclusivity for that of Congress.

B. Tracing Injury to Compliance with a Statutory Requirement

The Federal Circuit found Article III jurisdiction based on Caraco's alleged injury of "restrain[t] from the free exploitation of non-infringing goods," (Op. at 19-20), tracing that purported injury to Forest's listing of its patents in the Orange Book. (Id. at 21-22.) As Section II of Forest's Petition discusses in detail, tracing Caraco's purported injury to Forest offends Article III of the Constitution. Under the Hatch-Waxman Act, a brand manufacturer must identify to the FDA all patents covering a drug "with respect to which a claim of patent infringement could reasonably be asserted." 21 U.S.C. § 355(b)(1). Forest's compliance with this statute cannot render any alleged resulting injury attributable to Forest.

The Federal Circuit's holding that Caraco's injury is "fairly traceable" to Forest is inconsistent with its holding in Prasco, LLC v. Medicis Pharm. Corp., 537 F.3d 1329 (Fed. Cir. 2008), decided only four months after the Opinion. In Prasco, the patentee had marked its product as being covered by four patents pursuant to 35 U.S.C. § 287. Id. at 1334. The declaratory plaintiff sought declaratory judgments that its competing product did not infringe those four patents. Id. Section 287 provides that patentees may give notice to the public by marking their products, and further provides that if a patentee fails to so mark, "no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringement and

continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such notice." 35 U.S.C. § 287(a). The Federal Circuit determined that the patentee's marking of its product pursuant to 35 U.S.C. § 287(a) "[was] not a circumstance which supports finding an imminent threat of harm sufficient to create an actual controversy." Id. at 1334, 1340-41.

Just as the patentee in Prasco marked its product with its patents pursuant to 35 U.S.C. § 287, thereby alerting potential competitors to the possibility of an infringement suit, Forest listed its patents covering Lexapro® in the Orange Book pursuant to 21 U.S.C. § 355(b)(1). Both statutes are intended to provide notice of patents to potential infringers. Merck & Co., Inc. v. Hi-Tech Pharmacal Co., Inc., 482 F.3d 1317, 1319 (Fed. Cir. 2007) (noting that patents disclosed pursuant to § 355(b)(1) are "published in the 'Orange Book,' a register that provides notice of patents covering name brand drugs"); State Contracting & Eng'g Corp. v. Condotte Am., Inc., 346 F.3d 1057, 1073 (Fed. Cir. 2003) ("Section 287 of the Patent Act provides that patentees shall give notice of infringement by marking 'any patented article' . . . ."). But while the Prasco court found that the patentee's decision to mark its product was "irrelevant," the Federal Circuit found that Caraco's injury was in fact traceable to Forest's "decision" to list its patents in the Orange Book.

As Section II of the Petition details, Forest could not have omitted its patents from the Orange Book without suffering severe civil and criminal penalties. In contrast, in Prasco, the patentee could have chosen not to mark its product, the only potential consequence of which would be a limited damages recovery if it was successful in an infringement suit. 35 U.S.C. § 287(a). Therefore, Forest's listing of its patents in the Orange Book should be less persuasive of an intent to enforce its patents than the permissive marking of products under section 287. The Federal Circuit's conflicting decisions in the Opinion and Prasco warrant this Court's

review to clarify when, if ever, disclosing patents to potential competitors pursuant to a federal statute can satisfy a jurisdictional requirement under Article III.

IV. THE FEDERAL CIRCUIT CANNOT SUBSTITUTE ITS OWN POLICY CONCERNING THE 180-DAY EXCLUSIVITY PERIOD FOR THAT OF CONGRESS

The Opinion contradicts Congress's objectives in implementing the generic exclusivity award, and creates grounds for a new possible exclusivity trigger not endorsed by Congress: a declaratory action by a secondary ANDA filer brought solely to spoil the first-filer's exclusivity. No statutory basis exists for such an action, and such a result necessarily undermines the incentive to first-filers that invest significant resources to challenge or litigate the validity and/or infringement of a patent. The Opinion also generates unnecessary litigation by essentially forcing an innovator company to litigate its patents against every single ANDA challenger, even those it covenants not to sue.

With the Hatch-Waxman Act, Congress chose to reward the first ANDA filer to include a paragraph IV certification as an incentive to encourage generic manufacturers to risk challenging innovator companies' pharmaceutical patents. See 21 U.S.C. § 355(j)(5)(B)(iv) (1984). Congress reconsidered eligibility for generic exclusivity during the enactment of the Medicare Amendments.[4] Senator Hatch advocated for a "successful defense requirement" for generic exclusivity, under which Congress would reward the first

---

[4] Although the amendments to the 180-day generic exclusivity period effected by the Medicare Amendments are largely inapplicable here, Medicare Amendments, §1102(b), 117 Stat. at 2460, they are indicative of Congress's intent with respect to generic exclusivity.

ANDA filer to obtain a favorable court decision on the listed patent. 149 CONG. REC. S8691 (daily ed. June 26, 2003) (statement of Sen. Hatch). Congress rejected this approach, again indicating its intention that the first filer to include a paragraph IV certification should be eligible for the reward.[5]

IVAX, as the first generic manufacturer to file an ANDA for Lexapro® and challenge Forest's '941 patent, is eligible for the 180-day exclusivity award conferred by Congress. The Federal Circuit determined that Caraco should be allowed to maintain its declaratory judgment action solely to attempt to "activate" first-filer IVAX's Congressionally-mandated exclusivity period. This bias towards prematurely triggering the first ANDA filer's exclusivity, in essence favoring subsequent generic manufacturers which often file years later and have not expended the same resources or undertaken the same risks as the first filer, is contrary to Congress's policy with respect to the 180-day exclusivity period. Congress's balancing of the equities between the first generic challenger and subsequent generic challengers is crystallized in the 180-day exclusivity period, the starting point of which is critical to the first filer. Congress has clearly set forth the possible triggers for that 180-day exclusivity period in the Hatch-Waxman laws. The Federal Circuit may not substitute its own policy concerning the 180-day exclusivity period for that of Congress by creating a new exclusivity trigger. Only Congress can amend the Hatch-Waxman laws to address any perceived inequities with the 180-day generic exclusivity period; courts "must apply the statutory scheme as written." Teva Pharms. USA, Inc., 395 F.3d at 1338; see also Ranbaxy Labs. Ltd. v. Leavitt, 469 F.3d 120, 124 (D.C. Cir. 2006).

---

[5] After the Medicare Amendments, the first ANDA filer to challenge any of the NDA holder's listed patents is eligible for generic exclusivity. 21 U.S.C. § 355(j)(5)(B)(iv) (2003).

For various business reasons, including the desire to limit widespread litigation against ANDA filers, innovator pharmaceutical companies, such as Pfizer, may grant covenants not to sue in certain circumstances to avoid the expense of multiplicative patent litigation. The Federal Circuit's holding prevents an innovator company from choosing not to assert its patent, and essentially forces it to engage in expensive and time-consuming patent litigation against all generic challengers on every single listed patent solely so that the later-filing generic challenger can attempt to spoil the first filer's exclusivity. In some cases, there may be more than twenty different generic challengers to multiple patents with respect to a single innovator drug product. This result is not only unjust to both innovator and generic companies, but contrary to clear Congressional intent concerning the relevant Hatch-Waxman provisions. The Opinion is ripe for review and reversal.

CONCLUSION

For the foregoing reasons, this Court should grant Forest's petition for a writ of certiorari.

Respectfully submitted,

DIMITRIOS T. DRIVAS
(Counsel of Record)
JEFFREY J. OELKE
ADAM GAHTAN
BRENDAN G. WOODARD
WHITE & CASE LLP
1155 Ave. of the Americas
New York, NY 10036
(212) 819-8200

Counsel for Amicus Curiae Pfizer Inc.